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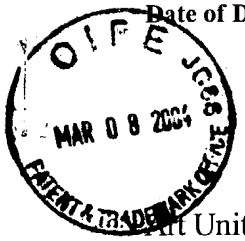


**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BOARD OF PATENT APPEALS AND INTERFERENCES**

Art Unit: 1644
Examiner: Patrick J. Nolan
Appellants: Founds, et al.
Serial No.: 09/465,444
Filed: December 16, 1999
For: MONOCLONAL ANTIBODY FOR ADVANCED GLYCOSYLATION ENDPRODUCTS IN BIOLOGICAL SAMPLES

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P.O. Box 1450
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# APPEAL BRIEF

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Claims 1-9 and 11-16, as set forth in Appendix 1, are pending. Claims 1-8, the claims as originally issued in U.S. Patent 5,698,197 ("the '197 patent") stand allowed. Claims 9 and 11-16 stand rejected under 35 U.S.C. 251 and are the subject of this appeal.

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"antibodies". Applicants do not intend an limitation of the claimed invention by use of that phrase.

AGEs are products from reactions of biological molecules and reducing sugars. AGEs produced in vivo, and the crosslinks resulting from such AGEs, have been implicated in stiffening and loss of function in tissues, organs and vessels, often associated with diabetes. The claimed invention is thus useful in detecting and treating such AGE's by providing a monoclonal antibody which reacts with and binds to such AGEs.

The antibody of the invention is characterized by its antigen binding capability, as measured by the binding competition by 6-aminocaprioic acid browned with glucose demonstrated by monoclonal antibody 4G9, produced by hybridoma 4G9, which is deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626. In a specific embodiment, the antibody is monoclonal antibody 4G9 produced by hybridoma 4G9 but is not limited to that antibody. In other embodiments, the antibody of the invention specifically binds serum-AGE lipids, LDL-AGE, Hb-AGE, collagen-AGE or serum-AGE peptides and proteins.

The '197 patent issued with 8 claims directed substantially to the monoclonal antibody 4G9 or antigen binding fragments thereof. In the present reissue application applicants wish to correct a defect in the '197 patent as which resulted in the '197 patent being partially or wholly inoperative as claiming less than the applicants had a right to claim. Thus, the present reissue application added new claims 9-16 which more fully define the invention applicants believe they were entitled to claim. Claim 10 was canceled during prosecution of the reissue application. The Examiner has maintained the rejection of claims 9 and 11-16 under 35 U.S.C. 251 asserting that applicants are attempting to recapture subject matter allegedly surrendered during prosecution of the '197 patent.

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Whether 35 U.S.C. § 251 allows applicants to add claims in a reissue application that are broader than the claims as issued yet narrower than the original canceled or amended claims.

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Claims 9 and 11-16 can be grouped together with respect to the issue on appeal.

## VIII. ARGUMENT

### 1. The Recapture Rule Does Not Prohibit Claims In Reissue Applications That Are Broader Than Issued Claims But Narrower Than Original Canceled or Amended Claims.

The prosecution of reissue patents is governed by primarily by 35 U.S.C. §251 which states:

> Whenever any patent is, though error without deceptive intention, deemed wholly or partially inoperative or invalid, by reason of a defective specification or drawing, **or by reason of the patentee claiming more or less than he had a right to claim in the patent**, the Director shall, on the surrender of such patent and the payment o the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue. 35 U.S.C. §251. (emphasis added).

Under the rules, an applicant may add claims in a reissue application that are broader than the claims as issued in the patent, when it is believed that the issued claims inadvertently excluded subject matter that applicant was entitled to claim. The Statute and PTO Rules require that any such broader claims be filed within two years of the issuance of the patent to be reissued. 35 U.S.C. §251, ¶ 4; 37 C.F.R. §1.173. In addition to the normal requirements for patentability (See, 37 C.F.R. §1.176), the PTO examines such broader claims to determine whether applicants are attempting to "recapture" any subject matter that was removed from claims during prosecution of the original patent See, M.P.E.P. §1412.02

As explained by the Court of Appeals for the Federal Circuit, the "recapture rule" is intended to prevent a patentee from regaining through reissue subject matter that was surrendered during prosecution by effectively holding that such a surrender "is not the type of correctable 'error' contemplated by the reissue statue." *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 1480 (Fed. Cir. 1998) (citing *Mentor Corp. v. Coloplast, Inc.* 998 F.2d 992, 995-996 (Fed. Cir. 1993)). Application of the recapture rule is a two step process, first determining whether and in what aspect the reissue claims are broader than the patent claims and second determining whether the broader aspects of the reissue claims relate to surrendered subject matter. *In re Clement,* 131 F.3d 1464, 1468-1469 (Fed. Cir. 1993).

However, not all broadening reissue claims raise issues under the recapture rule. The courts recognize that broader claims can be submitted to correct an error where an amendment during prosecution removes more than was needed to secure allowance of the claim. The Federal Circuit, and its predecessor court the Court of Customs and Patent Appeals, has clearly ruled that in such situations, as in the subject reissue application, the recapture rule is not implicated. As explained in *In re Richman,* 409 F.2d 269, 275 (C.C.P.A. 1969), an applicant might err without deceptive intention in adding a particular limitation where a less specific limitation regarding the same feature would have been sufficient to render the claims patentable. The Court in *Richman* instructs that the present situation requires comparison of the reissue claims to the original cancelled claims, not to the patented claims, noting that "the question raised is whether the appealed [reissue] claims are of the same scope as the cancelled claims, not whether they lack some specific recitation absent from the cancelled claims but included in the patent claims." 409 F.2d 269, 274. The recapture rule only bars the patentee from acquiring, through reissue, claims that are of the **same** or of **broader scope** than those claims that were canceled from the original application. *Ball Corporation v. United States*, 729 F.2d 1429, 1436 (1984). However, the patentee is free to acquire, through reissue, claims that are **narrower** in scope than the cancelled claims. *Id.* As the Federal Circuit confirmed in *In re Clement,* "when the reissue claim is narrower in all aspects [than the canceled or amended claim] the recapture rule does not apply." 131 F.2d at 1470.

**2. Reissue Claims 9 and 11-16 Are Not Barred By The Recapture Rule.**

The recapture rule does not prevent reissue 9 and 11-16, which are broader than the claims as issued but narrower than the claims as originally prosecuted with regard to a limitation directly at issue in the "surrendered" subject matter.

Applicants submit that the claims as pending in the instant reissue application are not of the same or broader scope as the claims cancelled (*i.e.* amended to delete "immunological binding characteristic of monoclonal antibody 4G9") from the original patent, and are in fact narrower in scope than the original, cancelled claims. Specifically, the scope of the reissue claims are narrower than the canceled claims and broader than the original patent claims (claims of intermediate scope) and were properly sought within two years after grant of the original

patent. Applicants sought the present reissue application based on the error that Applicants failed to appreciate the full scope of the invention without deceptive intent.

Applicants submit that pending claim 9 is of intermediate scope between originally filed claim 1, which was cancelled (*i.e.* amended via Examiner's Amendment), and claim 1 as issued.

Claim 1 as originally filed in parent application US Application Serial No. 08/483,186 recited (Emphasis Added):

> "A monoclonal antibody or antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs), which monoclonal antibody or antigen binding fragment thereof **demonstrates an immunological binding characteristic of monoclonal antibody 4G9** as produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626."

Claim 1 as issued in U.S. Patent 5,689,197 recited:

> "Monoclonal antibody 4G9 produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626, or an antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs)."

Claim 9 as pending in the instant reissue application recites (Emphasis on distinction from claim 1 as originally filed):

> "A monoclonal antibody or antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs), wherein the antibody or fragment is **selected such that antigen binding, measured by binding competition by 6-aminocaproic acid browned with glucose, matches that of a reference binding moiety which is monoclonal antibody 4G9** as produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626 or a fragment thereof corresponding to the antigen binding fragment."

The phrase "immunological binding characteristic" recited in originally filed claim 1, as defined in the specification "refers to the specificity, affinity, cross-reactivity, and other binding characteristics of an antibody" (*See*, Reissue application at Col. 7, lines 34-39). As defined, the phrase "immunological binding characteristic" includes many, if not all, the binding characteristics of a particular antibody. Applicants note that in parent application USSN 08/483,186 the Examiner rejected claim 1 for reciting "immunological binding characteristic of monoclonal antibody 4G9" under 35 U.S.C. §112, second paragraph, as being vague and indefinite in the Office Action mailed October 16, 1996. As such, Applicants submit that the

Examiner also recognized the broad nature of the phrase "immunological binding characteristic" to include many, if not all, the binding characteristics of monoclonal antibody 4G9.

Pending claim 9 recites a monoclonal antibody or fragment selected such that antigen binding matches that of monoclonal antibody 4G9 and further recites that the antigen binding is measured by binding competition by 6-aminocaproic acid browned with glucose. Applicants submit (Emphasis Added) that this subject matter and the scope of the reissue claim is clearly narrower than a monoclonal antibody with **any** immunological binding characteristic of monoclonal antibody 4G9 as recited in originally filed claim 1. Specifically, pending claim 9 is limited to one definite and specific immunological binding characteristic (affinity), as defined in the specification, and is further limited in that the affinity is measured only by a definite and specific mechanism and against one standard (binding competition by 6-aminocaproic acid browned with glucose). In fact, the instant application discloses several other potential binding competition measurements, such as, BSA, albumin and hemoglobin (*See*, Reissue application at Table 1, Col. 15, lines 45-58). Applicants submit that one of ordinary skill in the art could contemplate numerous antibodies which would fall within the scope of claim 1 as originally filed and yet fall outside the scope of pending claim 9. Therefore, Applicants submit that pending claim 9 is narrower than claim 1 as originally filed and broader than claim 1 as issued (*i.e.* intermediate cope).

The Examiner has cited *In re Clement*, *Ball Corporation* and *Hester Industries* in support of his rejection under 35 U.S.C. §251 (*See*, February 7, 2003 Final Office Action at pages 2-3). Applicants submit that the foregoing cases are distinguishable from the instant reissue application.

In *In re Clement*, applicants amended their originally filed claim to overcome prior art rejections. *In re Clement* at 1466. The claim sought in reissue was determined to be broader and narrower in areas relevant to the prior art rejections. *Id* at 1470. The court found that, on balance, the reissue claim was broader than it was narrower in a manner directly pertinent to the subject matter that Applicants surrendered throughout the prosecution, and as such the recapture rule barred the reissue claim. Id at 1471, 1472. In contrast to *In re Clement*, pending claim 9 in the instant reissue is not broader in any aspect directly pertinent to subject matter which was allegedly surrendered, in fact, as discussed *supra*, Applicants submit that pending reissue claim 9 is narrower in all aspects directly pertinent to the allegedly surrendered subject matter, and as

such should not be barred by the recapture rule.

In *Ball Corporation*, the claim sought in reissue was found to be broader in some aspects and narrower in others than the originally filed claims. *Ball Corporation* at 1437. However, the broader aspect of the claim sought in the reissue in *Ball Corporation* was different than the broader aspect sought in *In re Clement*. The broadening aspect in *Ball Corporation* was neither relevant to the prior art rejection or directly pertinent to surrendered subject matter. *Id* at 1438. As such, the court held that broader **aspect** of the reissue claims in *Ball Corporation* did not deprive them of the **fundamental narrowness** of scope relative to the cancelled claims (emphasis added). Thus the reissue claims were sufficiently narrower than the cancelled claims and therefore the effect of the recapture rule was avoided. *Id.* While Applicants submit pending claim 9 in the instant reissue is not broader in any aspect, as was the case in *Ball Corporation*, pending reissue claim 9 is sufficiently narrower, in all aspects directly pertinent to the allegedly surrendered subject matter, than originally filed claim 1, which was cancelled, to avoid the effect of the recapture rule and should be allowed.

In *Hester*, applicants amended the originally filed claims in view of prior art rejections to obtain allowance of the original patent claims. The court in *Hester* determined that such an amendment was an admission by the applicant that the scope of the claim was not in fact patentable. *Hester* at 1482. Further, since the claim sought in reissue was found to be broader in a manner directly pertinent to the subject matter that Applicants surrendered during prosecution, the reissue claim was barred by the recapture rule. Id at 1483, 1484. In contrast to *Hester*, the subject matter allegedly surrendered in the instant reissue application was not surrendered to overcome prior art. Nor did the Examiner's Amendment of original claim 1 result in an admission by the applicant that the scope of the claim was unpatentable. Further, and more importantly, in contrast to *Hester*, the pending reissue claims are of narrower scope, in all aspects directly pertinent to the allegedly surrendered subject matter, than original claim 1, which was cancelled. As such, the pending claims avoid the effect of the recapture rule and should be allowed.

Moreover, the Patent Board of Appeals found in *Ex parte Lumbard*, 47 U.S.P.Q. 523 (1940), that the reissue application at issue contained claims which were broader than those granted in the patent, but narrower, in at least one respect, than a claim presented and canceled during the prosecution of the original application on which the reissue patent sought to be issued.

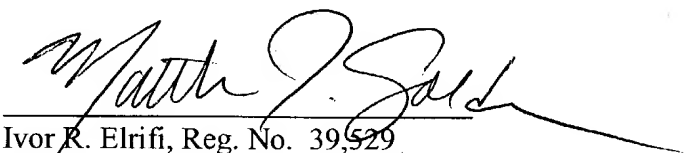
In holding the claims of the reissue application allowable, the Board noted that they were intermediate in scope between the broad claims withdrawn from the original application and the very limited claims allowed in the patent, and indicated that cancellation of the broad claims did not necessarily act as an estoppel against the assertion of the more limited claims, which were intermediate in scope between those canceled during prosecution and those allowed in the patent. *Id* at 523. Specifically, there was no claim withdrawn, cancelled, or amended in *Ex parte Lumbard* that was of the same scope as, or a more limited scope than, the claims of the reissue application. *Id.*

The decisions in *In re Clement*, *Ball Corporation*, *Hester Industries*, and *Ex parte Lumbard* clearly demonstrate that the patentee is free to acquire, through reissue, claims that are narrower in scope than those claims that were canceled from the original application and that recapture rule only bars the patentee from acquiring, through reissue, claims that are of the same or of broader scope than the cancelled claims. Thus, for the foregoing reasons, Applicants submit that pending claims 9 and 11-16 are narrower (and not of the same or broader scope) as the claim canceled from the original application. Thus, claims 9 and 11-16 are not an improper recapture of broadened claimed subject matter surrendered under 35 U.S.C. §251.

## IX. CONCLUSION

For the foregoing reasons, this Examiner's rejections under 35 U.S.C. § 251 should be reversed and claims 9 and 11-16 should be allowed.

Respectfully submitted,



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Dated: March 8, 2004

## APPENDIX 1: PENDING CLAIMS

1. (Allowed) Monoclonal antibody 4G9 produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626, or an antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs).

2. (Allowed) The monoclonal antibody or antigen binding fragment thereof of claim 1, which specifically binds to serum-AGE protein, serum-AGE lipids, serum-AGE peptides, LDL-AGE, Hb-AGE, or collagen-AGE.

3. (Allowed) A humanized or chimeric human-murine antibody of the monoclonal antibody of claim 1.

4. (Allowed) The antigen-binding fragment of the monoclonal antibody of claim 1, selected from the group consisting of a single chain Fv fragment, an F(ab')fragment, an F(ab) fragment, and an F(ab')2 fragment.

5. (Allowed) The monoclonal antibody or fragment thereof of claim 1, which is a murine IgG isotype antibody.

6. (Allowed) The labeled antibody wherein the antibody is the antibody of claim 1.

7. (Allowed) A hybridoma deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626.

8. (Allowed) A pharmaceutical composition containing an anti-AGE antibody in combination with a pharmaceutically acceptable carrier; wherein said anti-AGE antibody is the monoclonal antibody in accordance with any of claims 1-3 or 4.

9. (Previously Amended) A monoclonal antibody, or an antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs), wherein the antibody or fragment is selected such that antigen binding, measured by binding competition by 6-aminocaproic acid browned with glucose, matches that of a reference binding moiety which is monoclonal antibody 4G9 produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626 or a fragment thereof corresponding to the antigen binding fragment.

10. (Cancelled).

11. (Original) The monoclonal antibody or antigen binding fragment thereof of claim 9, which specifically binds to serum-AGE protein, serum-AGE lipids, serum-AGE peptides, LDL-AGE, Hb-AGE, or collagen-AGE.

12. (Previously Amended) A humanized or chimeric human-murine antibody of the monoclonal antibody of claim 9.

13. (Original) The antigen-binding fragment of the monoclonal antibody of claim 9, selected from the group consisting of a single chain Fv fragment, an F(ab')fragment, an F(ab) fragment, and an F(ab')2 fragment.

14. (Original) The monoclonal antibody or fragment thereof of claim 9, which is a murine IgG isotype antibody.

15. (Original) The labeled antibody wherein the antibody is the antibody of claim 9.

16. (Previously Amended) A pharmaceutical composition containing an anti-AGE antibody in combination with a pharmaceutically acceptable carrier; wherein said anti-AGE antibody is the monoclonal antibody in accordance with any of claims 9, 11-12 or 13.

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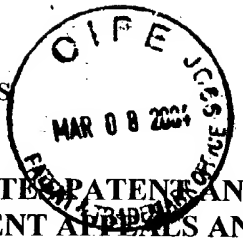


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**2. Reissue Claims 9 and 11-16 Are Not Barred By The Recapture Rule.**

The recapture rule does not prevent reissue 9 and 11-16, which are broader than the claims as issued but narrower than the claims as originally prosecuted with regard to a limitation directly at issue in the "surrendered" subject matter.

Applicants submit that the claims as pending in the instant reissue application are not of the same or broader scope as the claims cancelled (*i.e.* amended to delete "immunological binding characteristic of monoclonal antibody 4G9") from the original patent, and are in fact narrower in scope than the original, cancelled claims. Specifically, the scope of the reissue claims are narrower than the canceled claims and broader than the original patent claims (claims of intermediate scope) and were properly sought within two years after grant of the original

patent. Applicants sought the present reissue application based on the error that Applicants failed to appreciate the full scope of the invention without deceptive intent.

Applicants submit that pending claim 9 is of intermediate scope between originally filed claim 1, which was cancelled (*i.e.* amended via Examiner's Amendment), and claim 1 as issued.

Claim 1 as originally filed in parent application US Application Serial No. 08/483,186 recited (Emphasis Added):

> "A monoclonal antibody or antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs), which monoclonal antibody or antigen binding fragment thereof **demonstrates an immunological binding characteristic of monoclonal antibody 4G9** as produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626."

Claim 1 as issued in U.S. Patent 5,689,197 recited:

> "Monoclonal antibody 4G9 produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626, or an antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs)."

Claim 9 as pending in the instant reissue application recites (Emphasis on distinction from claim 1 as originally filed):

> "A monoclonal antibody or antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs), wherein the antibody or fragment is **selected such that antigen binding, measured by binding competition by 6-aminocaproic acid browned with glucose, matches that of a reference binding moiety which is monoclonal antibody 4G9** as produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626 or a fragment thereof corresponding to the antigen binding fragment."

The phrase "immunological binding characteristic" recited in originally filed claim 1, as defined in the specification "refers to the specificity, affinity, cross-reactivity, and other binding characteristics of an antibody" (*See,* Reissue application at Col. 7, lines 34-39). As defined, the phrase "immunological binding characteristic" includes many, if not all, the binding characteristics of a particular antibody. Applicants note that in parent application USSN 08/483,186 the Examiner rejected claim 1 for reciting "immunological binding characteristic of monoclonal antibody 4G9" under 35 U.S.C. §112, second paragraph, as being vague and indefinite in the Office Action mailed October 16, 1996. As such, Applicants submit that the

Examiner also recognized the broad nature of the phrase "immunological binding characteristic" to include many, if not all, the binding characteristics of monoclonal antibody 4G9.

Pending claim 9 recites a monoclonal antibody or fragment selected such that antigen binding matches that of monoclonal antibody 4G9 and further recites that the antigen binding is measured by binding competition by 6-aminocaproic acid browned with glucose. Applicants submit (Emphasis Added) that this subject matter and the scope of the reissue claim is clearly narrower than a monoclonal antibody with **any** immunological binding characteristic of monoclonal antibody 4G9 as recited in originally filed claim 1. Specifically, pending claim 9 is limited to one definite and specific immunological binding characteristic (affinity), as defined in the specification, and is further limited in that the affinity is measured only by a definite and specific mechanism and against one standard (binding competition by 6-aminocaproic acid browned with glucose). In fact, the instant application discloses several other potential binding competition measurements, such as, BSA, albumin and hemoglobin (*See*, Reissue application at Table 1, Col. 15, lines 45-58). Applicants submit that one of ordinary skill in the art could contemplate numerous antibodies which would fall within the scope of claim 1 as originally filed and yet fall outside the scope of pending claim 9. Therefore, Applicants submit that pending claim 9 is narrower than claim 1 as originally filed and broader than claim 1 as issued (*i.e.* intermediate cope).

The Examiner has cited *In re Clement*, *Ball Corporation* and *Hester Industries* in support of his rejection under 35 U.S.C. §251 (*See*, February 7, 2003 Final Office Action at pages 2-3). Applicants submit that the foregoing cases are distinguishable from the instant reissue application.

In *In re Clement*, applicants amended their originally filed claim to overcome prior art rejections. *In re Clement* at 1466. The claim sought in reissue was determined to be broader and narrower in areas relevant to the prior art rejections. *Id* at 1470. The court found that, on balance, the reissue claim was broader than it was narrower in a manner directly pertinent to the subject matter that Applicants surrendered throughout the prosecution, and as such the recapture rule barred the reissue claim. Id at 1471, 1472. In contrast to *In re Clement*, pending claim 9 in the instant reissue is not broader in any aspect directly pertinent to subject matter which was allegedly surrendered, in fact, as discussed *supra*, Applicants submit that pending reissue claim 9 is narrower in all aspects directly pertinent to the allegedly surrendered subject matter, and as

such should not be barred by the recapture rule.

In *Ball Corporation*, the claim sought in reissue was found to be broader in some aspects and narrower in others than the originally filed claims. *Ball Corporation* at 1437. However, the broader aspect of the claim sought in the reissue in *Ball Corporation* was different than the broader aspect sought in *In re Clement*. The broadening aspect in *Ball Corporation* was neither relevant to the prior art rejection or directly pertinent to surrendered subject matter. *Id* at 1438. As such, the court held that broader **aspect** of the reissue claims in *Ball Corporation* did not deprive them of the **fundamental narrowness** of scope relative to the cancelled claims (emphasis added). Thus the reissue claims were sufficiently narrower than the cancelled claims and therefore the effect of the recapture rule was avoided. *Id.* While Applicants submit pending claim 9 in the instant reissue is not broader in any aspect, as was the case in *Ball Corporation*, pending reissue claim 9 is sufficiently narrower, in all aspects directly pertinent to the allegedly surrendered subject matter, than originally filed claim 1, which was cancelled, to avoid the effect of the recapture rule and should be allowed.

In *Hester*, applicants amended the originally filed claims in view of prior art rejections to obtain allowance of the original patent claims. The court in *Hester* determined that such an amendment was an admission by the applicant that the scope of the claim was not in fact patentable. *Hester* at 1482. Further, since the claim sought in reissue was found to be broader in a manner directly pertinent to the subject matter that Applicants surrendered during prosecution, the reissue claim was barred by the recapture rule. Id at 1483, 1484. In contrast to *Hester*, the subject matter allegedly surrendered in the instant reissue application was not surrendered to overcome prior art. Nor did the Examiner's Amendment of original claim 1 result in an admission by the applicant that the scope of the claim was unpatentable. Further, and more importantly, in contrast to *Hester*, the pending reissue claims are of narrower scope, in all aspects directly pertinent to the allegedly surrendered subject matter, than original claim 1, which was cancelled. As such, the pending claims avoid the effect of the recapture rule and should be allowed.

Moreover, the Patent Board of Appeals found in *Ex parte Lumbard*, 47 U.S.P.Q. 523 (1940), that the reissue application at issue contained claims which were broader than those granted in the patent, but narrower, in at least one respect, than a claim presented and canceled during the prosecution of the original application on which the reissue patent sought to be issued.

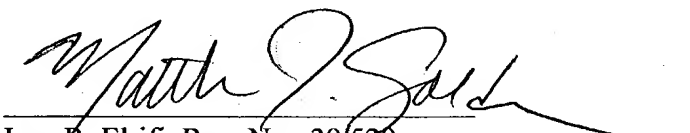
In holding the claims of the reissue application allowable, the Board noted that they were intermediate in scope between the broad claims withdrawn from the original application and the very limited claims allowed in the patent, and indicated that cancellation of the broad claims did not necessarily act as an estoppel against the assertion of the more limited claims, which were intermediate in scope between those canceled during prosecution and those allowed in the patent. *Id* at 523. Specifically, there was no claim withdrawn, cancelled, or amended in *Ex parte Lumbard* that was of the same scope as, or a more limited scope than, the claims of the reissue application. *Id.*

The decisions in *In re Clement*, *Ball Corporation*, *Hester Industries*, and *Ex parte Lumbard* clearly demonstrate that the patentee is free to acquire, through reissue, claims that are narrower in scope than those claims that were canceled from the original application and that recapture rule only bars the patentee from acquiring, through reissue, claims that are of the same or of broader scope than the cancelled claims. Thus, for the foregoing reasons, Applicants submit that pending claims 9 and 11-16 are narrower (and not of the same or broader scope) as the claim canceled from the original application. Thus, claims 9 and 11-16 are not an improper recapture of broadened claimed subject matter surrendered under 35 U.S.C. §251.

## IX. CONCLUSION

For the foregoing reasons, this Examiner's rejections under 35 U.S.C. § 251 should be reversed and claims 9 and 11-16 should be allowed.

Respectfully submitted,



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## APPENDIX 1: PENDING CLAIMS

1. (Allowed) Monoclonal antibody 4G9 produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626, or an antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs).

2. (Allowed) The monoclonal antibody or antigen binding fragment thereof of claim 1, which specifically binds to serum-AGE protein, serum-AGE lipids, serum-AGE peptides, LDL-AGE, Hb-AGE, or collagen-AGE.

3. (Allowed) A humanized or chimeric human-murine antibody of the monoclonal antibody of claim 1.

4. (Allowed) The antigen-binding fragment of the monoclonal antibody of claim 1, selected from the group consisting of a single chain Fv fragment, an F(ab')fragment, an F(ab) fragment, and an F(ab')2 fragment.

5. (Allowed) The monoclonal antibody or fragment thereof of claim 1, which is a murine IgG isotype antibody.

6. (Allowed) The labeled antibody wherein the antibody is the antibody of claim 1.

7. (Allowed) A hybridoma deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626.

8. (Allowed) A pharmaceutical composition containing an anti-AGE antibody in combination with a pharmaceutically acceptable carrier; wherein said anti-AGE antibody is the monoclonal antibody in accordance with any of claims 1-3 or 4.

9. (Previously Amended) A monoclonal antibody, or an antigen binding fragment thereof reactive with in vivo produced advanced glycosylation endproducts (AGEs), wherein the antibody or fragment is selected such that antigen binding, measured by binding competition by 6-aminocaproic acid browned with glucose, matches that of a reference binding moiety which is monoclonal antibody 4G9 produced by hybridoma 4G9, deposited with the American Type Culture Collection (ATCC) and assigned Accession Number CRL 11626 or a fragment thereof corresponding to the antigen binding fragment.

10. (Cancelled).

11. (Original) The monoclonal antibody or antigen binding fragment thereof of claim 9, which specifically binds to serum-AGE protein, serum-AGE lipids, serum-AGE peptides, LDL-AGE, Hb-AGE, or collagen-AGE.

12. (Previously Amended) A humanized or chimeric human-murine antibody of the monoclonal antibody of claim 9.

13. (Original) The antigen-binding fragment of the monoclonal antibody of claim 9, selected from the group consisting of a single chain Fv fragment, an F(ab')fragment, an F(ab) fragment, and an F(ab')2 fragment.

14. (Original) The monoclonal antibody or fragment thereof of claim 9, which is a murine IgG isotype antibody.

15. (Original) The labeled antibody wherein the antibody is the antibody of claim 9.

16. (Previously Amended) A pharmaceutical composition containing an anti-AGE antibody in combination with a pharmaceutically acceptable carrier; wherein said anti-AGE antibody is the monoclonal antibody in accordance with any of claims 9, 11-12 or 13.